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PATENT APPLICATION
Docket No.: 10209.383

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	CLAUDE JARAKAE JENSEN, ET AL.	
Serial No.:	10/036,152	
Filed:	December 31, 2001	RESPONSE TO OCTOBER 19, 2004 OFFICE ACTION
Title:	METHOD FOR TREATING CARBON TETRA-CHLORIDE INDUCED LIVER DAMAGE BY ADMINISTERING MORINDA CITRIFOLIA	
Examiner:	Susan Coe—Art Unit 1654	

RENEWED PETITION UNDER 37 CFR § 1.37(b)

Mail Stop: Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This correspondence is responsive to the Notice of Petition Dismissal mailed February 4, 2005, for the above-referenced case. Applicant hereby submits the Request for Continued Examination and respectfully requests reconsideration of this dismissal.

Also enclosed is a copy of the Amendment and Response filed November 12, 2004.

Please credit any over payment or charge any additional fees to Deposit Account No. 500843 of the undersigned.

Should there be any questions, the Examining Attorney is respectfully invited to contact the undersigned.

DATED this 3 day of March 2005.

Respectfully submitted,

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Commissioner for Patents
Post Office Box 1450
Alexandria, Virginia 22313-1450

AMENDMENT AND RESPONSE

Dear Sir:

This correspondence is responsive to the Office Action mailed October 19, 2004, for the above-referenced application. The following Amendment and Response addresses every rejection set forth in the Office Action, thus placing the application in condition for allowance.

AMENDMENTS TO THE CLAIMS

Applicant respectfully requests amendment of the claims as follows:

1. (currently amended) A method for inhibiting hepatotoxin-induced liver damage in mammals ~~by blocking carcinogen-induced DNA adduct formation, scavenging free radicals, quenching lipid hydroproxides, and selectively inhibiting COX-2, said method~~ comprising the steps of:

administering, to a patient, at least two ounces of a formulation comprising:

processed *Morinda citrifolia* juice; and

processed *Morinda citrifolia* puree, wherein said composition blocks DNA adduct formation, scavenges free radicals, quenches lipid hydroperoxides and selectively inhibits COX-2. ~~to inhibit effects of carbon tetrachloride within said patient.~~

2. (previously presented) The method of claim 1, wherein said *Morinda citrifolia* is administered in dosages comprising at least two ounces of processed *Morinda citrifolia* juice twice daily on an empty stomach for a period of at least two months.

3. (previously presented) The method of claim 1, wherein said *Morinda citrifolia* is in juice form.

4. (previously presented) The method of claim 1, wherein said *Morinda citrifolia* is in solid form.

5. (previously presented) The method of claim 1, wherein said *Morinda citrifolia* is in powder form.

6. (previously presented) The method of claim 1, wherein said formulation comprises said *Morinda citrifolia* present in an amount between about 0.1 and 80 percent by weight.

7. (previously presented) The method of claim 1, wherein said formulation comprises said *Morinda citrifolia* in an amount between about 0.1 and 5 percent by weight, said formulation being administered for a period of at least seven days.

8. (previously presented) The method of claim 1, wherein said formulation comprises said *Morinda citrifolia* in an amount between about 5 and 10 percent by weight, said formulation being administered for a period of at least seven days.

9. (previously presented) The method of claim 1, wherein said formulation comprises said *Morinda citrifolia* in an amount between about 10 and 15 percent by weight, said formulation being administered for a period of at least seven days.

10. (previously presented) The method of claim 1, wherein said formulation comprises said *Morinda citrifolia* in an amount between about 15 and 20 percent by weight, said formulation being administered for a period of at least seven days.

11. (previously presented) The method of claim 1, wherein said formulation comprises said *Morinda citrifolia* in an amount between about 20 and 25 percent by weight, said formulation being administered for a period of at least seven days.

12. (previously presented) The method of claim 1, wherein said formulation comprises said *Morinda citrifolia* in an amount between about 25 and 30 percent by weight, said formulation being administered for a period of at least seven days.

13. (previously presented) The method of claim 1, wherein said formulation comprises said *Morinda citrifolia* in an amount between about 30 and 35 percent by weight, said formulation being administered for a period of at least seven days.

14. (previously presented) The method of claim 1, wherein said formulation comprises said *Morinda citrifolia* in an amount between about 35 and 40 percent by weight, said formulation being administered for a period of at least seven days.

15. (previously presented) The method of claim 1, wherein said formulation comprises said *Morinda citrifolia* in an amount between about 40 and 45 percent by weight, said formulation being administered for a period of at least seven days.

16. (previously presented) The method of claim 1, wherein said formulation comprises said *Morinda citrifolia* in an amount between about 45 and 50 percent by weight, said formulation being administered for a period of at least seven days.

17. (previously presented) The method of claim 1, wherein said formulation comprises said *Morinda citrifolia* in an amount between about 50 and 55 percent by weight, said formulation being administered for a period of at least seven days.

18. (previously presented) The method of claim 1, wherein said formulation comprises said *Morinda citrifolia* in an amount between about 55 and 60 percent by weight, said formulation being administered for a period of at least seven days.

19. (previously presented) The method of claim 1, wherein said formulation comprises said *Morinda citrifolia* in an amount between about 60 and 65 percent by weight, said formulation being administered for a period of at least seven days.

20. (previously presented) The method of claim 1, wherein said formulation comprises said *Morinda citrifolia* in an amount between about 65 and 70 percent by weight, said formulation being administered for a period of at least seven days.

21. (previously presented) The method of claim 1, wherein said formulation comprises said *Morinda citrifolia* in an amount between about 70 and 75 percent by weight, said formulation being administered for a period of at least seven days.

22. (previously presented) The method of claim 1, wherein said formulation comprises said *Morinda citrifolia* in an amount between about 75 and 80 percent by weight, said formulation being administered for a period of at least seven days.

23. (previously added) The method of claim 1, wherein said hepatotoxin is carbon tetrachloride (CC14).

24. (currently amended) A method of inhibiting hepatotoxin-induced liver damage in mammals ~~by blocking carcinogen-induced DNA adduct formation, scavenging free radicals, quenching lipid hydroproxides, and selectively inhibiting COX-2, said method~~ comprising the steps of:

administering, to a patient, at least two ounces of a formulation comprising:

processed *Morinda citrifolia* juice; and

processed *Morinda citrifolia* puree twice daily, wherein said composition blocks DNA adduct formation, scavenges free radicals, quenches lipid hydroperoxides and selectively inhibits COX-2. ~~to inhibit effects of carbon tetrachloride within said patient.~~

25. (previously presented) The method of claim 24, wherein said formulation comprises ten percent said *Morinda citrifolia*, said formulation being administered for a period of at least seven days.

26. (previously presented) The method of claim 24, wherein said formulation comprises said *Morinda citrifolia* in an amount between about 0.1 and 80 percent by weight, said formulation being administered for a period of at least seven days.

27. (currently amended) A method for inhibiting cancerous growth, in the liver of mammals, at the initiation stages of carcinogenesis by blockage of carcinogen-DNA adduct formation, ~~scavenging free radicals, quenching lipid hydroproxides, and selectively inhibiting COX-2,~~ said method comprising the steps of:

administering, to a patient, at least two ounces of a formulation comprising:

processed *Morinda citrifolia* juice; and

processed *Morinda citrifolia* puree twice daily, wherein said composition blocks DNA adduct formation, scavenges free radicals, quenches lipid hydroperoxides and selectively inhibits COX-2. ~~to inhibit effects of carbon tetrachloride within said patient.~~

28. (previously presented) The method of claim 27, wherein said formulation comprises said *Morinda citrifolia* in an amount between about 0.1 and 80 percent by weight, said formulation being administered for a period of at least seven days.

29. (previously added) A method for blocking carcinogen-DNA adduct formation during early stage carcinogenesis, said method comprising the steps of:

administering, to a patient, at least two ounces of a formulation comprising processed *Morinda citrifolia* twice daily.

30. (previously added) The method of claim 29, wherein said formulation comprises said *Morinda citrifolia* in an amount between about 0.1 and 80 percent by weight, said formulation being administered for a period of at least seven days.

31. (currently amended) A method for inhibiting and preventing hepatic carcinogens from causing liver damage, ~~by blocking carcinogen induced DNA adduct formation, scavenging free radicals, quenching lipid hydroproxides, and selectively inhibiting COX-2, said method~~ comprising the steps of:

administering, to a patient, at least two ounces of a formulation comprising:

processed *Morinda citrifolia* juice; and

processed *Morinda citrifolia* puree twice daily, wherein said composition blocks DNA adduct formation, scavenges free radicals, quenches lipid hydroperoxides and selectively inhibits COX-2. ~~to inhibit effects of carbon tetrachloride within said patient~~.

32. (previously added) The method of claim 31, wherein said formulation comprises said *Morinda citrifolia* in an amount between about 0.1 and 80 percent by weight, said formulation being administered for a period of at least seven days.

33. (previously presented) The method of claim 31, wherein liver damage is inhibited and prevented by destroying said hepatic carcinogens.

REMARKS

In the Office Action mailed from the United States Patent and Trademark Office on October 19, 2004, the Examiner rejected claims 29 and 30 under 35 U.S.C. § 103(a) as being unpatentable over Japanese Patent Application No. 08217686 A ("JP '686'"); and claims 1-28 and 31-33 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,039,559 ("the '559 patent") in view of U.S. Patent Application No. 2002/0068102 (filed Dec. 1, 2000) ("the '102 application"). Accordingly, Applicant respectfully provides the following:

Rejections under 35 U.S.C. § 103

An invention is unpatentable under Section 103(a) "if the differences between the subject matter sought to be patented over the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains." To establish a *prima facie* case of obviousness, three criteria must be met.

> First there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must beach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); MPEP § 2142.

JP '686 does not teach or suggest all of the claim limitations present in claims 29 and 30. JP '686 teaches using a product extracted, with organic solvents, from dried roots of *Morinda citrifolia* to eradicate heliobacter pylori. Claim 27 of the present invention from which claims 29 and 30 depend has been amended to claim, "[a] method for inhibiting cancerous growth ... comprising the steps of: administering, to a patient, at least two ounces of a formulation comprising: processed *Morinda citrifolia* juice; and processed *Morinda citrifolia* puree twice

daily, wherein said composition blocks DNA adduct formation, scavenges free radicals, quenches lipid hydroperoxides and selectively inhibits COX-2." JP '686 does not teach using *Morinda citrifolia* juice. JP '686 does not teach using *Morinda citrifolia* juice with *Morinda citrifolia* puree. Extract from dried roots is not juice combined with puree. Further, JP '686 teaches a method of eradicating heliobacyter pylori. There is no suggestion in JP '686 to use *Morinda citrifolia* to inhibit cancerous growth. Because JP '686 does not teach all of the elements claimed in the present invention, Applicant respectfully submits that the proposed claims are neither anticipated nor rendered obvious by JP '686.

Claims 1-28 and 31-33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,039,559 ("the '559 patent") and U.S. Application No. 2002/0068102 (filed Dec. 1, 2000) ("the '102 application"). The invention entity for the present application and the '102 application are the same. Stephen P. Story's name was unintentionally, and without deceptive intent, omitted from the present application. Attached is a copy of the petition to have Stephen P. Story's name added to the present application. Because the effective date of the present invention, December 31, 2001, is less than one year from the earliest priority date for the '102 application, November 29, 2001, the '102 application is not prior art that can be cited against the present application.

The '559 patent alone does not teach or suggest all of the claim limitations of claims 1-28 and 31-33. The '559 patent teaches aliphatic carboxylic acid esters of Vitamin E which exhibit the biological activities of Vitamin E. The '559 application suggests that physiological damage resulting from the administration of carbon tetrachloride to animal is thought to be due to free radicals. The claims of the current application have been amended to include elements not present in the prior art cited. Specifically, the present invention claims a method comprising

"administering, to a patient, at least two ounces of a formulation comprising: processed *Morinda citrifolia* juice; and processed *Morinda citrifolia* puree twice daily, wherein said composition blocks DNA adduct formation, scavenges free radicals, quenches lipid hydroperoxides and selectively inhibits COX-2." The '559 application does not suggest utilizing the claimed formulation of *Morinda citrifolia*. Because the '102 application is a product of the same inventive entity as the present application, and because the '559 patent does not teach all of the elements claimed in the present invention, Applicant respectfully submits that the proposed claims are neither anticipated nor rendered obvious by the '559 patent and the '102 application.

CONCLUSION

Based on the foregoing, Applicant respectfully submits that the deficiencies in the application have been corrected and that the proposed claims are neither anticipated nor rendered obvious by the prior art reference cited by the Examiner. As such, Applicant believes that the claims are now in a condition for allowance, and action to that end is respectfully requested.

If any impediments to the allowance of this application for patent remain after the above amendments and remarks are entered, the Examiner is invited to initiate a telephone conference with the undersigned attorney of record.

DATED this 12 day of November, 2004.

Respectfully submitted,

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